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10/541,074	06/29/2005	Antonius Cornelis Boersen	BOERSEN3	4057

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EXAMINER	
TOUSSAINT, DALILA	
ART UNIT	PAPER NUMBER
1794	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,074	BOERSEN ET AL.	
	Examiner	Art Unit	
	DALILA TOUSSAINT	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *13-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The substitute abstract filed December 12, 2009 has been entered.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. **Claims 1, 3-7, and 18-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Peters et al. WIPO Publication WO 00/72692 A1**, in view of **Henningfield et al. US Patent 6790288 B2** and **McCarthy et al. US Patent 5350590**.

a. Referring to claims 1 and 18, Peters disclose a method for producing whey powder, comprising the steps of:

Providing a whey concentrate containing lactose with a dry matter content of at least 45% (Peters; page 3, line 33).

Peters disclose heating the whey concentrate containing lactose to a temperature of at least 85 °C and maintaining the whey concentrate at said temperature (Peters; page 7, line 30).

Peters disclose crystallizing lactose (Peters; page 8, line 3).

Peters disclose using a Spin Flash dryer wherein the process of finely dispersing the whey concentrate and drying the finely dispersed whey concentrate to form a whey powder with sufficient free moisture for recrystallization (Peters; page 13, line 7-8 and page 14, line 4-6).The steps b) and c) are preformed in the Spin Flash dryer as the instant claim 9 recites.

Peters disclose a process wherein the heating step takes place rapidly (Peters; page 7, line 1-5), however, Peters is silent about heating for a period between 0.25 minute and 5 minutes. Henningfield discloses the concentrate from the heating step having a residence time of approximately 4 minutes in a heating device (Henningfield; column 7, line 14-20). McCarthy discloses a concentrate containing crystallized lactose, being heated to about 93 °C for about 1 minute (McCarthy; column 15, line 55). Based on the secondary references, it would have been obvious to one of ordinary skill in the art at the time the invention was made, in rapid heating of dairy product, to include the heating period such as in the instant claim. One would have been motivated to do so to prevent large aggregates from forming during heat treatment (McCarthy; column 16, line 68).

b. Referring to claims 3-5 and 19-20, Peters disclose heating the whey concentrate containing lactose to a temperature of at least 90 °C and maintaining the whey concentrate at said temperature (Peters; page 6, line 23 and page 7, line 30). Peters disclose a process wherein the heating step takes place rapidly (Peters; page 7, line 1-5), however, Peters is silent to heating for a period of between 0.25 minute and 5 minutes.

Henningfield disclose the concentrate from the heating step having a residence time of approximately 4 minutes in the heating device (Henningfield; column 7, line 14-20). McCarthy discloses a concentrate containing crystallized lactose, being heated to about 93 °C for about 1 minute (McCarthy; column 15, line 55). Based on the secondary references, it would have been obvious to one of ordinary skill in the art at the time the invention was made, in rapid heating of dairy product, to include the heating period such

as in the instant claim. One would have been motivated to do so to prevent large aggregates from forming during heat treatment (McCarthy; column 16, line 68).

c. Referring to claim 6, Peters disclose prior to step b) a dry matter content of at least 55% is created in the whey concentrate (Peters; page 7, line 36-38).

d. Referring to claim 7, Peters disclose the whey concentrate is a concentrate of whey permeate (Peters; page 8, line 6-7).

4. **Claim 2** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Peters et al. US Publication WO 00/72692 A1**, **Henningfield et al. US Patent 6790288 B2**, **McCarthy et al. US Patent 5350590** and in view of **Peebles et al. US Patent 2,088,608**.

e. Referring to claim 2, Peters disclose the method wherein at the end of the spray-drying step, the moisture in the dry powder (Karl Fisher) is about 1-5%.

However, Peter does not explicitly disclose a limitation on the moisture of the dry powder as recited in the instant claim wherein "the free moisture content is between 8% and 13%". Henningfield disclose a free-moisture in the crystal slurry being reduced to 2% in the spray-drying step (Henningfield; column 7, line 49). Peebles disclosure recites having a "typical instance where the free moisture content of the spray dried material about 12 to 14%" (Peebles; page 2, column 1, line 43-45).

Regarding the spray drying step taking place in Peters, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the moisture range of the secondary references to get product as dried as possible. One would have been motivated to do so to prevent wetness and tacky character of the material (Peebles; page 2, column 2, line 67-68).

5. **Claims 8-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Peters et al. US Publication WO 00/72692 A1**, **Henningfield et al. US Patent 6790288 B2**, **McCarthy et al. US Patent 5350590** in view of **Peebles et al. US Patent 2088608** and **Keller US patent 7241465 B2** .

f. Referring to claim 8, Peters disclose the method wherein fine particles which originate from the drying step are entrained with the drying gas (Peters; figure 2, #17), however, Peter does not explicitly disclose the gas filtered with the aid of a filter.

Peebles discloses delivering the suspension of the drying gas to a separator i.e. filter of the bag type (Peebles; page 3, column 2, line 5-15). Keller US patent 7241465 B2 teaches the process of spray drying highly concentrate lactose wherein the disclosure recites in column 14, line 31-40:

> In the preferred embodiment shown in FIG. 1, exhaust air comes out of the top of the dryer 24 through exhaust air outlet lines 37a and 37b which feed into a baghouse 38. Also, in an alternative embodiment (not shown), a single outlet line will feed into the baghouse 38. The exhaust air contains fines, which are generated in the dryer 24, 24'. The exhaust air is drawn into the baghouse 38 by a blower 40, which draws air through the baghouse 38 and exhausts the air.

Based on the secondary references, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Peters to filter the entrained gas as a way to recover the fine particles in the gas. One would have been motivated to do so to suitably separate the finished product from the exhaust (Keller; column 14, line 53-56).

g. Referring to claim 9, Peters et al. teaches:

(1) The method of claim1, wherein steps c) and d) are carried out by means of a spray-drying process, in which the whey concentrate is atomized in a drying chamber and drying gas is passed through the atomized whey concentrate, with the spray-dried whey concentrate being collected as a powder and the drying gas being discharged via a drying gas outlet (Peters et al.; page 13, line 7-20 and figure 2, #17).

h. Referring to claim 10, Peters fail to explicitly disclose the method wherein auxiliary gas is fed to the discharged drying gas in a quantity and at a temperature and relative atmospheric humidity which are such that the combination of the discharged drying gas with entrained fine particles and the supplied auxiliary gas is outside the range in which the entrained fine particles are sticky.

Peebles discloses delivering the suspension of the drying gas to a separator i.e. filter of the bag type (Peebles; page 3, column 2, line 5-15) wherein the spray drying apparatus comprising one or more conduits that communicate with the chamber for the introduction of hot air or the like and conduits that enable the withdrawal of exhaust near the upper portion of the chamber (Peebles; page 2, column 2, line 15-20). The drying gas temperature and other factors are carefully controlled to produce less moisture in the final product (Peebles; page 2, column 2, line 1-5).

Keller US patent 7241465 B2 teaches the process of spray drying highly concentrate lactose wherein the disclosure recites in column 14, line 31-57:

> In the preferred embodiment shown in FIG. 1, exhaust air comes out of the top of the dryer 24 through exhaust air outlet lines 37a and 37b which feed into a baghouse

> 38. Also, in an alternative embodiment (not shown), a single outlet line will feed into the baghouse 38. The exhaust air contains fines, which are generated in the dryer 24, 24'. The exhaust air is drawn into the baghouse 38 by a blower 40, which draws air through the baghouse 38 and exhausts the air. The fines in the exhaust air from the dryer 24 are collected in the baghouse and redirected back into the dryer 24 through an inlet line 42 through which ambient air or, alternately, dehumidified ambient air is blown by a further blower 44.
>
> In the processing system 2 shown in FIG. 1 dried HLAF solids are discharged from the dryer through an outlet line 52 interconnected to a line 54, which passes to a cooling tube 56 and is fed into a baghouse 58 via a feed line 57. In the initial system shown in FIG. 1, the baghouses will have membrane coated bags, preferably Gore-Tex.RTM. or comparable membrane coated bags. The air streams coming from the dryer 24 through the various lines 52, 54 and 57 are all drawn by a further blower 60.

Regarding the discharged drying gas of Peters, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include an auxiliary gas conduits of the secondary references to entrain the fine particles in the gas. One would have been motivated to do so to increase the collection of fine particles in the entrained air (Keller; column 14, line 53-56).

i. Referring to claim 11, Peters disclose the method wherein dry particles are fed to the discharged dry gas (Peters; figure 2, #17).

j. Referring to claim 12, Peters disclose the method wherein the auxiliary gas and/or the dry particles are fed to an inlet, located in the vicinity of a drying chamber, of the drying gas discharge (Peters; figure 2, #12 and #17).

Response to Arguments

Applicant's arguments with respect to claims 9-10 have been considered but are moot in view of the new ground(s) of rejection.

On pages 9-14, Applicant argues that Peters' liquid product dry solid content of at least 40% is further concentrated to a large solid concentration as possible, wherein subsequently the concentration is later crystallized. Peters heating step is above the crystallization temperature and the crystallization of lactose occurs after the transfer of liquid into a flash separator. Whereas, Henningfield heating step is below the crystallization temperature of the liquid, wherein, the method permits simultaneous concentrating and crystallization.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller,* 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck* & Co., 800 F.2d 1091,231 USPQ 375 (Fed. Cir.1986). For example, applicant argues that Peters and Henningfield do not teach the same heating and that Peters does not teach the claimed product. These arguments are not convincing as the rejections were made over a combination of references and not over one of the cited references alone.

Also, Peters disclose the process of further concentrating the liquid and subsequently crystallizing the lactose which is the same process. Applicant specifications disclose the same on

page 9, line 5-15. In reference to arguments on page 11, the prior art teaches the steps of a), b), c) and d) of Applicant claim 1. There is not a clear patentable distinction between the prior art and Applicant claims.

Peters, disclose that the liquid in the heating steps are in the range of 65-90 °C (page 7, line 30) and is "transferred directly to a buffer tank for crystallization" (page 8, line9). Thus after concentration the liquid whey concentration is subjected to crystallization (page 9, line 33).

Henningfield's disclosure recites in column 3, line 30-32, "progressive heating at a temperature above 40 °C, but below the maximum temperature for crystallization of α-lactose monohydrate from the liquid." Therefore this includes that the heating of aqueous solutions can reach up to the maximum temperature of 93.5 °C (Henningfield; column 1, line 25). Henningfield provides explicit, analogous, teaching where the concentrate from the heating step has a residence time of approximately 4 minutes (Henningfield; column 7, line 14-20). Thus, Henningfield is able to provide a non-caking and free-flowing product (Henningfield; column 6, line 54-55).

Applicant argues Peters teaches above the crystallization point and Henningfield teach below the crystallization point. However as described above, it is clear the references range during the heating step overlap and therefore one skilled in the art would have motivation to apply the teachings of Henningfield to Peters method.

On page 15, Applicant argues that the references Peters, Henningfield and Peebles rejections are irrelevant due to the arguments presented above.

In response to applicant's argument, the rejection made in view of Peters, Henningfield and Peebles are valid as disclose above in response to arguments presented and are not withdrawn.

On page 15, Applicant argues that Peters temperature range is neither disclosed nor suggested as in the instant claims. Peters avoid the range because of Maillard reaction and teaches away from such high temperatures.

In response to applicant's argument, the reference of Peters disclose a heating step wherein the temperature is at least 90 °C (Peters; page 6, line 23 and page 7, line 30). As such, all the disclosures in a reference must be evaluated for what they fairly teach one of ordinary skill in the art even though the art teachings relied upon are phrased in terms of a non-preferred embodiment or even as being unsatisfactory for the intended purpose. *In re Boe, 148 USPQ 507 (CCPA 1966); In re Smith, 65 USPQ 167 (CCPA 1945); In re Nehrenberg, 126 USPQ 383 (CCPA 1960); In re Watanabe, 137 USPQ 350 (CCPA 1963).*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DALILA TOUSSAINT whose telephone number is (571)270-7088. The examiner can normally be reached on Monday - Friday, 8:00 a.m. - 5:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on (571)272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. SAYALA/
Primary Examiner, Art Unit 1794

DT